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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,244	02/18/2004	David M. Sabatini	WIBL-P01-010	5817

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ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,244	SABATINI ET AL.	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 34-38, drawn to a polypeptide and complex, classified in class 530, subclass 350.

II. Claims 6-7, and 25-27, drawn to an antibody and a kit comprising the antibody, classified in class 530, subclass 387.1.

III. Claims 8-21, and 31-33, drawn to nucleic acid, vector, host cell, method of making protein, and a kit comprising the nucleic acid, classified in class 435, subclass 69.1.

IV. Claims 22-24, drawn to a method of detecting a protein, classified in class 435, subclass 7.1.

V. Claims 28-30, drawn to a method of detecting the nucleic acid, classified in class 435, subclass 6.

VI. Claims 39-47, drawn to a method of identifying a compound that modulates activity of the protein, classified in class 435, subclass 7.1.

VII. Claims 48-51, drawn to a method of inhibiting activity of the protein, classified in class 514, subclass 12.

VIII. Claims 52-57, drawn to a method of treating or preventing disorder that is responsive to the protein modulation, classified in class 514, subclass 12.

XIX. Claims 58-60, drawn to a transgenic mouse, classified in class 800, subclass 295+.

Applicant is required to make further election:

Group I is directed to distinct proteins, and Group III directed to distinct nucleic acids.

The amino acid sequences in Group I are distinct one from the other because they are composed of different amino acid sequences (SEQ ID NO:3 or SEQ ID NO:6). See Sequence Listing, p. 4-8, and 9-10. Also, the nucleic acids encoding amino acid sequences in Group I are composed of different nucleotides, and therefore have distinct compositions (SEQ ID NO:2 or SEQ ID NO:5). See Sequence Listing, p. 3-4, and p.9.

The nucleic acid sequences of Group III (SEQ ID NO:2 or SEQ ID NO:5) are composed of different nucleotides, and therefore have distinct compositions. See Sequence Listing p. 3-4, and 9.

The Applicant is required to elect **one** amino acid sequence from Group I upon election of Group I, or **one** nucleic acid sequence from Group III upon election of Group III. **This is NOT an election of species.**

The inventions are distinct, each from the other because of the following reasons:

The proteins of Invention I are related to the antibodies of Invention II by virtue of being the cognate antigen necessary for the production of antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because the protein can be used in another and materially

different process from the use for the production of the antibody, such as in a pharmaceutical composition, or to assay or purify the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the receptor protein. Therefore, the inventions are distinct.

The protein of invention I and nucleic acid of invention III are patently distinct inventions for the following reasons. Proteins, which are composed of amino acids, and nucleic acids, which are composed of purine and pyrimidine units, are structurally distinct molecules. In the present invention, the nucleic acid of Invention III does not necessarily encode the proteins of Invention I. Also, the information provided by the nucleic acid of invention III can be used to make a materially different protein than that of Invention I. Moreover, the proteins of invention I can be recovered from a natural source using biochemical means, such as affinity chromatography. Therefore, the inventions are distinct.

The nucleic acid of Invention III and the antibody of Invention II are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are different compounds having different compositions and functions. Therefore, the inventions are distinct.

Invention I and IV/VI/VII/VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of Invention I, can be used in different methods as described in Inventions IV/VI/VII/VIII. Therefore, the inventions are distinct.

Invention II and Inventions IV/VI/VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody of Invention II cannot be used in methods of Inventions IV/VI/VII/VIII. Therefore, the inventions are distinct.

Invention III and Inventions IV/VI/VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the nucleic acid of Invention III cannot be used in Invention IV/VI/VII/VIII. Therefore, the inventions are distinct.

Inventions IV/VI/VII/VIII are related by virtue of the protein that is used in all the claimed methods. However, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each method is distinct from each other because they perform distinct functions, and have different modes of operation such as: method of detection of the protein (Invention IV), method of identifying a compound that modulates activity of the protein (Invention VI), method of inhibiting activity of the protein (Invention VII), and a method of

treating or preventing disorder that is responsive to the protein (Invention VIII). Therefore, the inventions are distinct.

Invention V and Inventions IV/VI/VII/VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention V uses the nucleic acid, and Inventions IV/VI/VII/VIII use the protein, therefore the inventions are not capable of being used together because they use different products and have different end effects.

Invention V and Invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention V can utilize different nucleic acid, and Invention III can be utilized for making recombinant proteins. Therefore, the inventions are distinct.

Invention V and Inventions I/II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the protein of Invention I and the antibody of Invention II cannot be used in a method of Invention V. Therefore, the inventions are distinct.

Inventions IV/V/VI/VII/VIII and Invention IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention XIX is directed to gene therapy, where Inventions IV/V/VI/VII/VIII are directed to methods that are distinct from gene therapy of Invention IX. The distinct inventions use different products, possess different modes of operation, and are classified separately. Therefore, the inventions are distinct.

Inventions I/II/III and Invention IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions I and II cannot be used in Invention IX. Therefore, the inventions are distinct.

Invention III and Invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention III can be used in different methods as suggested by Invention V. Therefore, the inventions are distinct.

Because the inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. or call 866-217-9197.

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ROBERT A. WAX
PRIMARY EXAMINER
AU 1653